

DCP Timeline Tool

Demonstration of Potential Features

February 4, 2002

**Bill McCurry
ScenPro, Inc.**

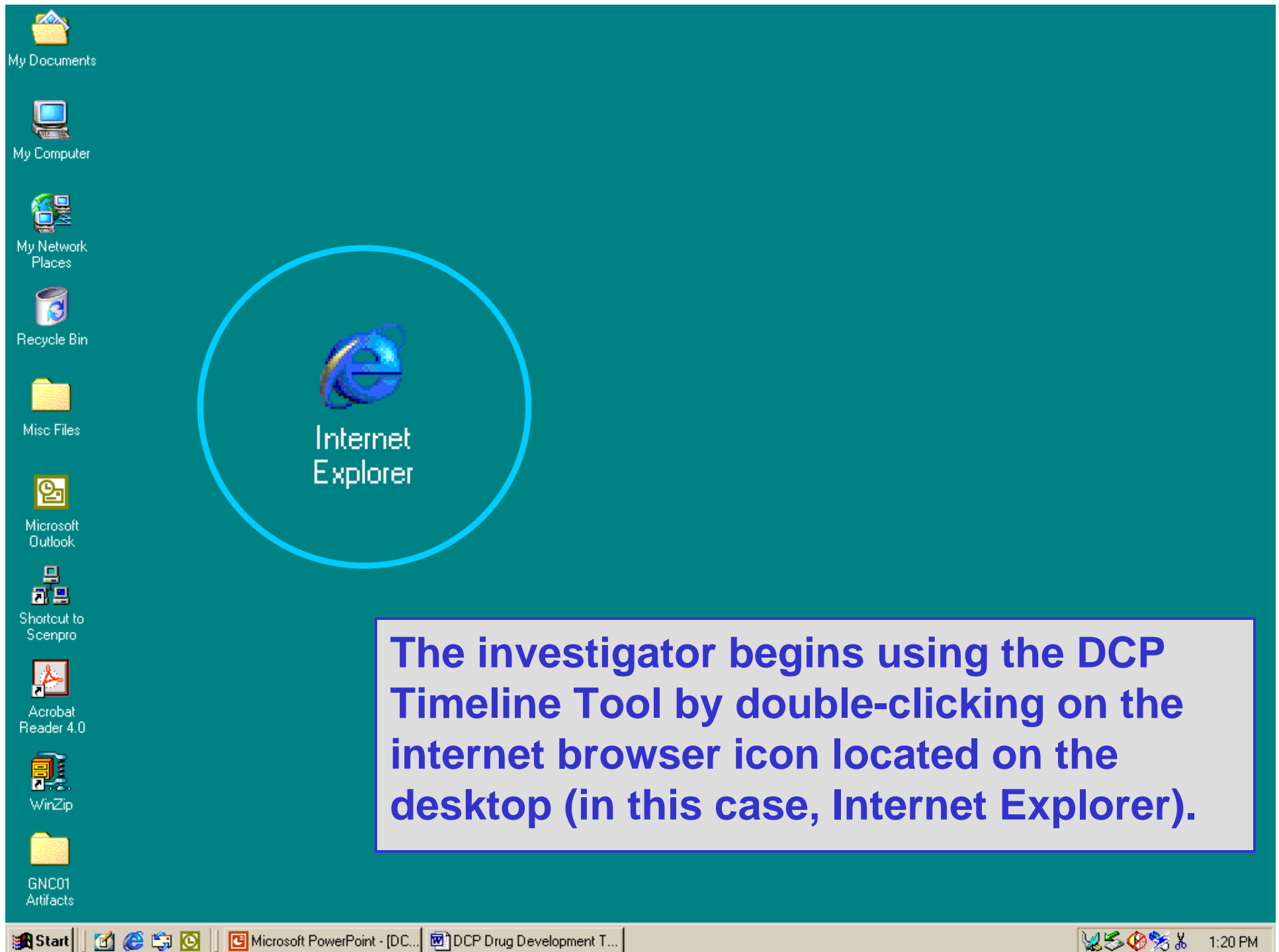


Development Overview

- Internet-based application can be built to display a temporal view of DCP clinical trial data
- Significant re-use of existing technology is possible
- Will require Knowledge Acquisition to document DCP user requirements
- Will work closely with Oracle to identify and access database resources
- Can develop initial prototype application and then revise based on ongoing DCP evaluation
- This presentation shows screens from a simple prototype that ScenPro has developed for DCP

Tool Features

- Accessible via an Internet browser
- Secured by password and 128 bit data encryption
- View study milestones in Gantt charts over time
- Select studies based on Agent, Medical Monitor, PI, Institution, Keyword, or other search criteria
- Track studies throughout their lifecycle
- Easily share short notes by attaching them to studies
- Create user-defined tasks tied to studies
- Display, sort and compare multiple studies
- View accrual data (if stored in database)




Division of Cancer Prevention Home Page - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Back Forward Stop Home Search Favorites History Print View Source

Address <http://azurite:8080/taskview/logon.jsp> Go Links Fool DCP Tool



Division of
Cancer Prevention

[home](#)
[dictionary](#)
[site map](#)
[search](#)

Site Map

Preventing and Detecting Specific Cancers

- Breast cancer
- Colorectal cancer
- Lung cancer
- Prostate cancer
- More...

Lifestyle and Preventing Cancer

- Diet, food, and nutrition
- Smoking
- More...

Prevention and Detection Clinical Trials

- Understand detection
- Ongoing
- Search for
- More...

Events and Meetings

- Weekly colloquy (Colloquy)
- Upcoming
- NCI calendar
- More...

Key Initiatives in Prevention and Detection

- Early Detection Research Network (EDRN)
- Community Clinical Oncology Program (CCOP)
- Lung Screening Study
- Prostate, Lung, Colorectal, and Ovarian Cancer Screening Trial (PLCO)
- Cancer Prevention Fellowship Program
- More...

Information for Researchers

Features/Updates

- Breast Cancer Prevention Study STAR Reaches Mid-Point of Recruitment
- Interview with Dr. Leslie Ford about STAR
- DCP grantee recognized by TIME magazine as one of "America's Best" clinical scientists

Office and research groups

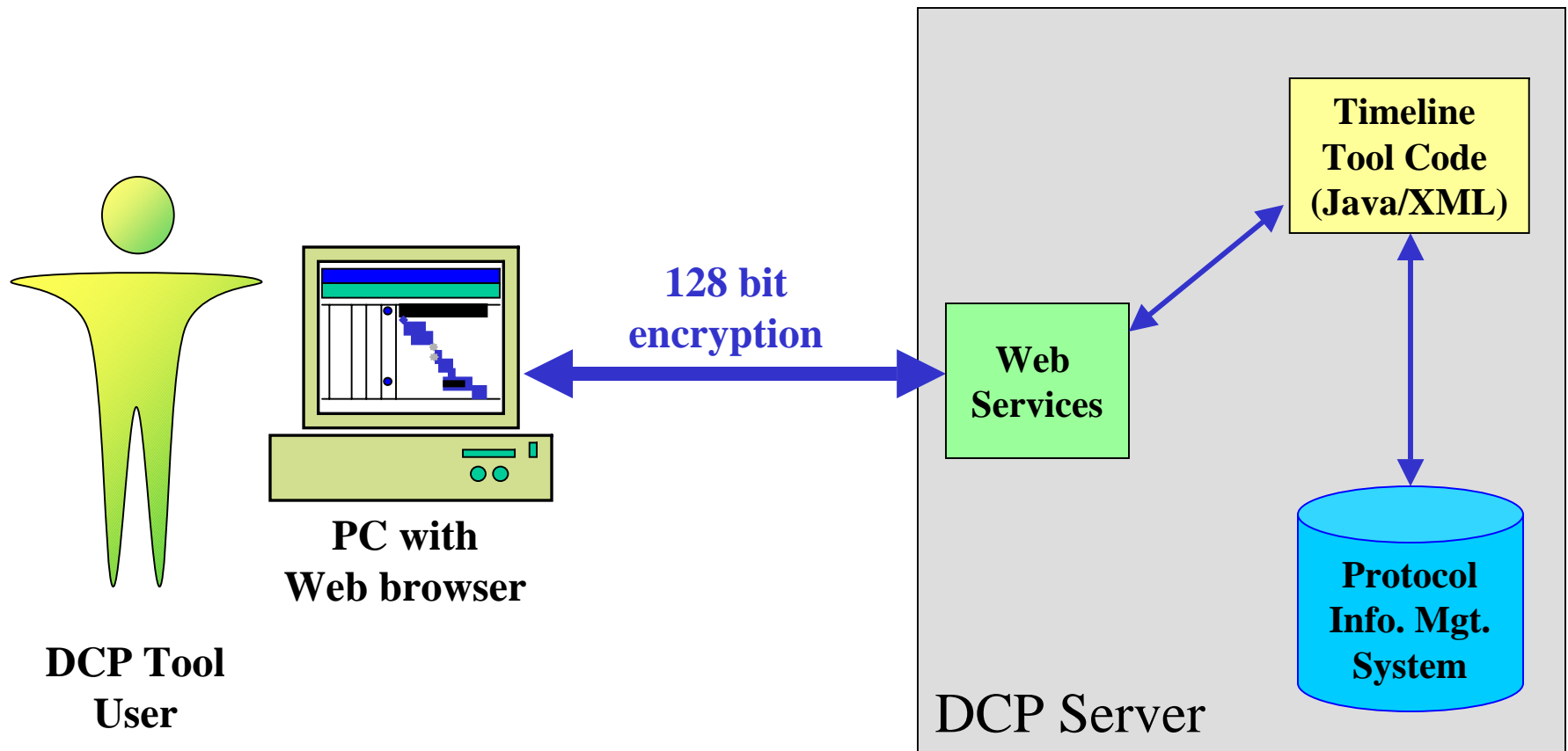
<http://cancer.gov/prevention/sitemap.html>

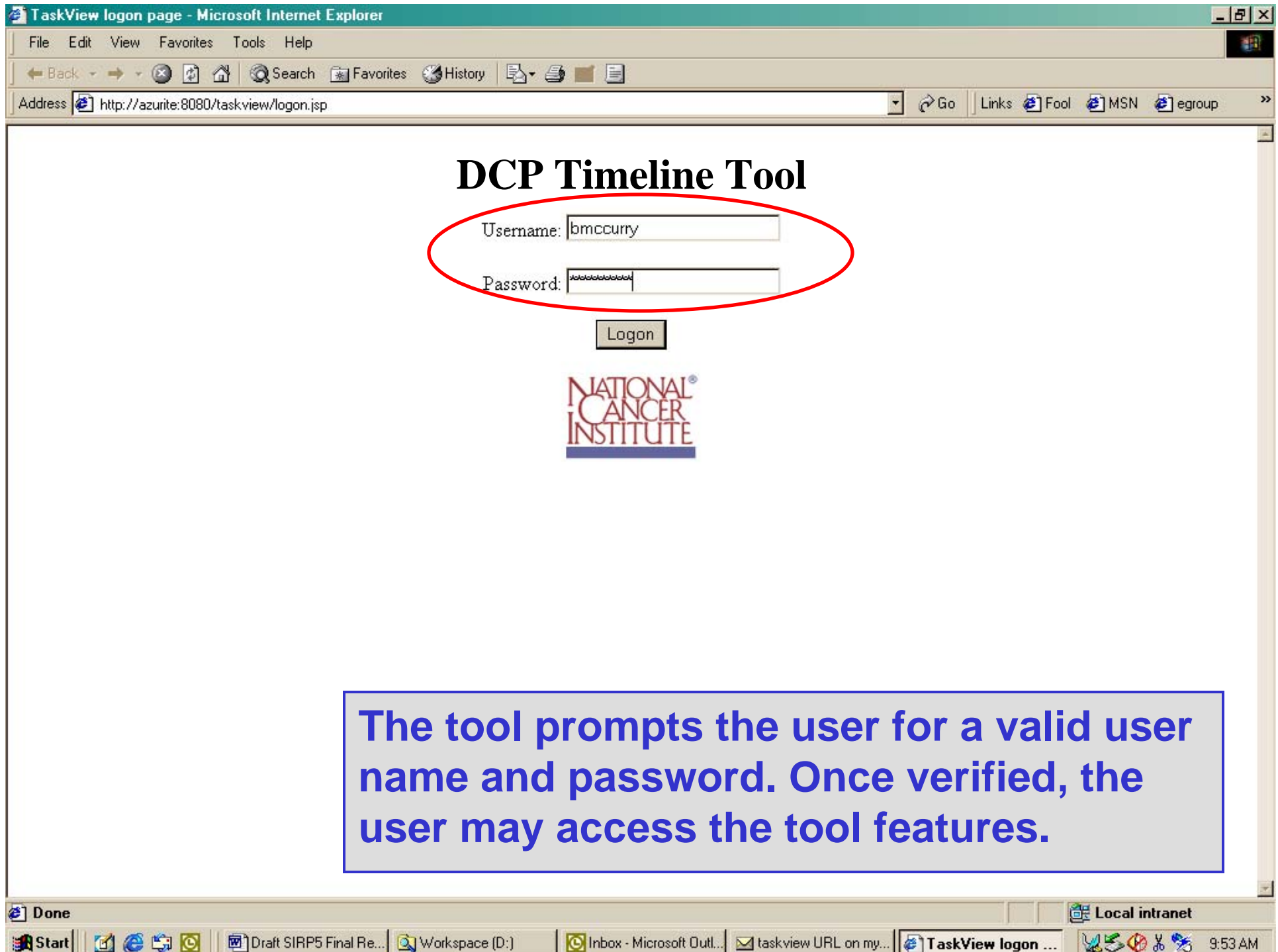
Start | Microsoft PowerPoint - [DC...] | DCP Drug Development T... | Division of Cancer Pr...

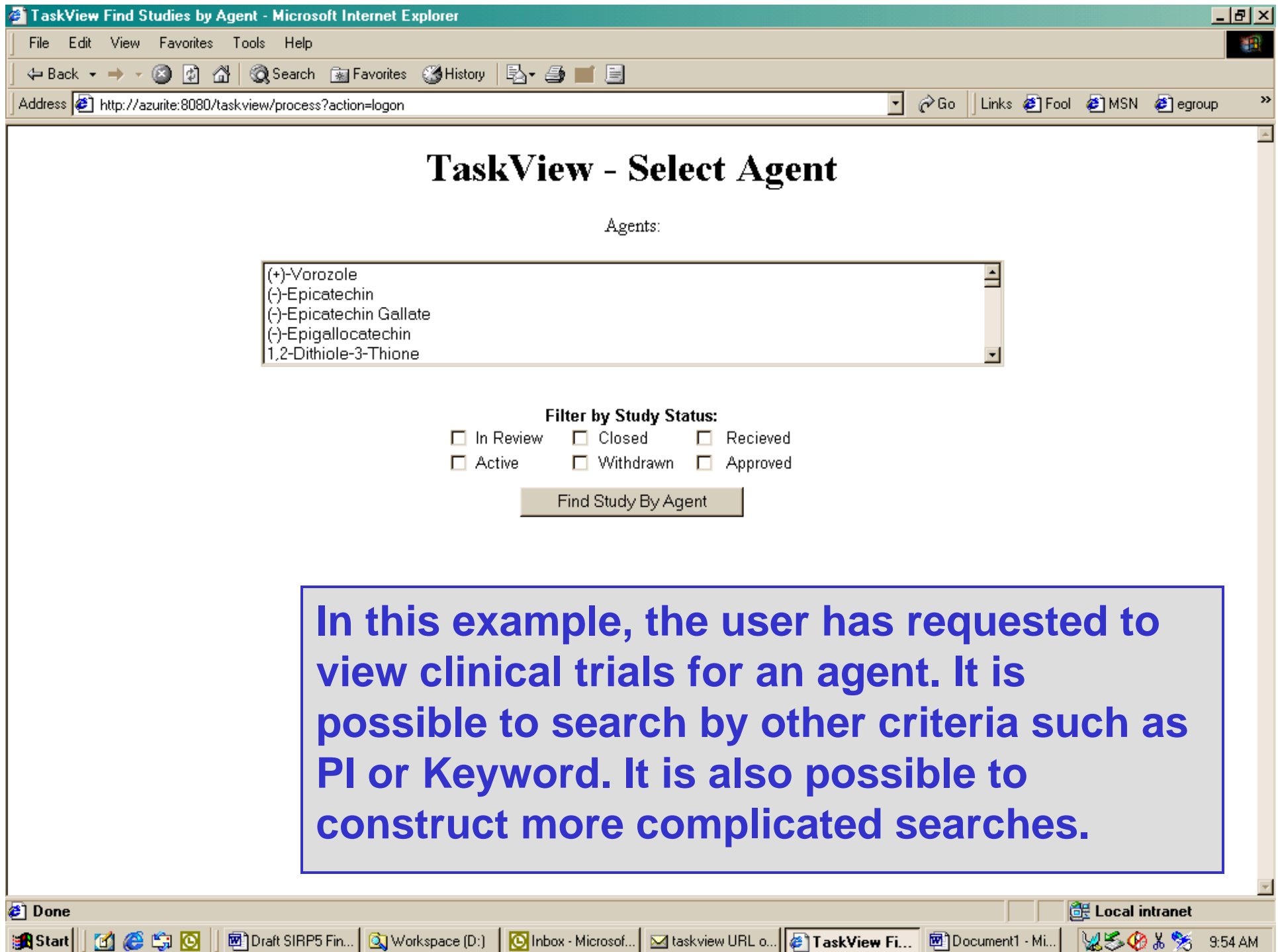
Internet 1:38 PM

Once the browser is open, the user selects the DCP Timeline Tool logon. The user may type in the URL, set a bookmark, or use a link if one is set up from the user's home page.

High-Level Architecture







TaskView Find Studies by Agent - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Back Forward Stop Home Search Favorites History Print

Address <http://azurite:8080/taskview/process?action=logon> Go Links Fool MSN egroup

TaskView - Select Agent

Agents:

- Catechin Gallate
- Celecoxib**
- Chaetomelic Acid A
- Cicloxolone
- Citric Acid, Calcium Salt

Filter by Study Status:

☒ In Review ☐ Closed ☐ Recieved
☒ Active ☐ Withdrawn ☒ Approved

Find Study By Agent

Here the user has chosen to show all the studies involving the agent Celecoxib. This list of agents is being read directly from the PIMS database and is therefore always up to date.

Done Start Local intranet 9:55 AM

TaskView Find Studies by Agent - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Back Forward Stop Home Search Favorites History Print

Address <http://azurite:8080/taskview/process?action=logon> Go Links Fool MSN egroup

TaskView - Select Agent

Agents:

- Catechin Gallate
- Celecoxib**
- Chaetomelic Acid A
- Cicloxolone
- Citric Acid, Calcium Salt

Filter by Study Status:

- ☒ In Review
- ☐ Closed
- ☐ Recieved
- ☒ Active
- ☐ Withdrawn
- ☒ Approved

Find Study By Agent

Here the user filters the search by asking for only studies with statuses of “In Review,” “Active,” or “Approved.” Other types of filters are possible, depending on user interest and information in the PIMS database.

Done Start Local intranet

Draft SIRP5 Fin... Workspace (D:) Inbox - Microsof... taskview URL o... TaskView Fi... Document1 - Mi... 9:55 AM

TaskView Find Studies by Agent - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Back Forward Stop Home Search Favorites History Print

Address <http://azurite:8080/taskview/process?action=logon> Go Links Fool MSN egroup

TaskView - Select Agent

Agents:

- Catechin Gallate
- Celecoxib**
- Chaetomelic Acid A
- Cicloxolone
- Citric Acid, Calcium Salt

Filter by Study Status:

☒ In Review ☐ Closed ☐ Recieved
☒ Active ☐ Withdrawn ☒ Approved

Find Study By Agent

The user clicks on the “Find Studies” button. This retrieves from the PIMS database a list of studies that meet the search criteria.

Done Start Local intranet 9:55 AM

TaskView- Studies by Agent - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Back Forward Stop Home Search Favorites History Print Copy Paste

Address http://azurite:8080/taskview/process?action=studiesByAgent Go Links Fool MSN egroup

TaskView - Select Studies

Studies Found: 13

Document #	Study Title	Version	Latest Version	Select
N01-CN-65118	Phase II Multiple- Dose Safety And Efficacy Clinical Study Of Nonsteroidal Antiinflammatory Based Regimens In Adenomatous Polyposis Coli Patients (Celecoxib, SC-58635)	# 0	Latest Version	Chart <input checked="" type="checkbox"/>
N01-CN-85183-Step 1	Phase II Clinical Study Of A Cox-II Inhibitor In Skin Cancer. Clinical Trial Of Celecoxib In Subjects With Actinic Keratosis	# 0	Latest Version	Chart <input checked="" type="checkbox"/>
N01-CN-75021-41	Phase I/II Multiple-Dose Safety And Efficacy Study Of A Selective Inhibitor Of Cyclooxygenase-2 Or NSAID (SC-58635)	# 0	Latest Version	Chart <input type="checkbox"/>
N01-CN-85183-Step 2	Phase II Clinical Study Of A Cox-II Inhibitor In Skin Cancer. Clinical Trial Of Celecoxib In Subjects With Actinic Keratosis~2	# 0	Latest Version	Chart <input type="checkbox"/>
N01-CN-85185	Phase II Randomized Placebo-Controlled, Double-Blind Study Of Celecoxib (SC-58635) In Barrett's Esophagus Patients	# 0	Latest Version	Chart <input type="checkbox"/>
N01-CN-85186~2	Phase II Randomized Placebo-Controlled, Double-Blind Study Of Celecoxib (SC-58635) In Barrett's Esophagus Patients	# 0	Latest Version	Chart <input type="checkbox"/>
N01-CN-95015~2	Phase III Randomized Placebo-Controlled, Double-Blind Study Of Celecoxib (SC-58635) In Barrett's Esophagus Patients	# 0	Latest Version	Chart <input type="checkbox"/>

The list shows the number of studies found and the document number, version, and title of each study.

Done Local intranet

Start Draft SIRP5 Fin... Workspace (D:) Inbox - Microsof... taskview URL o... TaskView- S... Document1 - Mi... 9:55 AM

TaskView- Studies by Agent - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Back Forward Stop Home Search Favorites History Print Copy Paste

Address http://azurite:8080/taskview/process?action=studiesByAgent Go Links Fool MSN egroup

The user may select one or more studies for which he would like Gantt charts created...

			Latest Version	Chart <input type="checkbox"/>
			Latest Version	Chart <input type="checkbox"/>
N01-CN-95040	A Three Arm Phase II Chemoprevention Trial In Adenomatous Polyposis Coli Patients	# 15	Latest Version	Chart <input type="checkbox"/>
N01-CN-95129	A Phase II Randomized, Placebo-Controlled Trial Of Celecoxib In Men Pre-Prostatectomy For Clinically Localized Adenocarcinoma Of The Prostate: Evaluation Of Drug-Specific Biomarker Modulation	# 0	Old Version	Chart <input checked="" type="checkbox"/>
N01-SC-91019~2	A Pilot Study Of Selenomethionine And Celecoxib As Chemopreventive Agents For Esophageal Squamous Dysplasia In Linxian, China	# 0	Latest Version	Chart <input checked="" type="checkbox"/>
U19-CA-81888	Basal Cell Carcinoma Chemoprevention In BCNS Patients: Celecoxib	# 0	Latest Version	Chart <input type="checkbox"/>
U19-CA-81888-Bickers	Basal Cell Carcinoma Chemoprevention In BCNS Patients: Celecoxib~2	# 0	Latest Version	Chart <input type="checkbox"/>
N01-CN-95129	A Phase II Randomized, Placebo-Controlled Trial Of Celecoxib In Men Pre-Prostatectomy For Clinically Localized Adenocarcinoma Of The Prostate: Evaluation Of Drug-Specific Biomarker Modulation	# 15	Old Version	Chart <input type="checkbox"/>

Chart Studies

Done Start Draft SIRP5 Fin... Workspace (D:) Inbox - Microsof... taskview URL o... TaskView- S... Document1 - Mi... Local intranet 9:56 AM

TaskView- Studies by Agent - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Back Forward Stop Home Search Favorites History Print

Address http://azurite:8080/taskview/process?action=studiesByAgent Go Links Fool MSN egroup

(SC-50055) in Barret's Esophagus Patients

...and then click on the Chart Studies button to create the Gantt charts.

			Latest Version	Chart <input type="checkbox"/>
			Latest Version	Chart <input type="checkbox"/>
N01-CN-95040	A Three Arm Phase II Chemoprevention Trial In Adenomatous Polyposis Coli Patients	# 15	Latest Version	Chart <input type="checkbox"/>
N01-CN-95129	A Phase II Randomized, Placebo-Controlled Trial Of Celecoxib In Men Pre-Prostatectomy For Clinically Localized Adenocarcinoma Of The Prostate: Evaluation Of Drug-Specific Biomarker Modulation	# 0	Old Version	Chart <input checked="" type="checkbox"/>
N01-SC-91019~2	A Pilot Study Of Selenomethionine And Celecoxib As Chemopreventive Agents For Esophageal Squamous Dysplasia In Linxian, China	# 0	Latest Version	Chart <input checked="" type="checkbox"/>
U19-CA-81888	Basal Cell Carcinoma Chemoprevention In BCNS Patients: Celecoxib	# 0	Latest Version	Chart <input type="checkbox"/>
U19-CA-81888-Bickers	Basal Cell Carcinoma Chemoprevention In BCNS Patients: Celecoxib~2	# 0	Latest Version	Chart <input type="checkbox"/>
N01-CN-95129	A Phase II Randomized, Placebo-Controlled Trial Of Celecoxib In Men Pre-Prostatectomy For Clinically Localized Adenocarcinoma Of The Prostate: Evaluation Of Drug-Specific Biomarker Modulation	# 15	Old Version	Chart <input type="checkbox"/>

Chart Studies

Done Start Draft SIRP5 Fin... Workspace (D:) Inbox - Microsof... taskview URL o... TaskView- S... Document1 - Mi... Local intranet 9:56 AM

TaskView- Online Gantt Chart

Task Name	Start Date	Finish Date	Notes	03/00	12/00	09/01	06/02	03/03	12/03	09/04	06/05	03/06
A Phase II Randomized, Placebo-Controlled Trial Of Celecoxib In Men Pre-Prostatectomy For Clinically Localized Adenocarcinoma Of The Prostate: Evaluation Of Drug-Specific Biomarker Modulation, N01-CN-95129	Mar 9, 2000	Mar 13, 2006	*									
Pre-Activation Tasks	Mar 9, 2000	Mar 13, 2006	*									
Post-Activation Tasks	Apr 10, 2000	Feb 8, 2003	*									
Accrual Planned	Apr 10, 2000	Jul 10, 2001	*									
Accrual Begins	Sep 19, 2000	Sep 19, 2000	*									
Accrual Completed	Dec 19, 2001	Dec 19, 2001	*									
First Evaluation	Dec 19, 2001	Feb 13, 2002	*									
Study Completed	Feb 13, 2002	Feb 8, 2003	*									

The Gantt chart displays a timeline on which are displayed the start and finish dates of study-related tasks.

TaskView- Online Gantt Chart

Task Name	Start Date	Finish Date	Notes	03/00	12/00	09/01	06/02	03/03	12/03	09/04	06/05	03/06
A Phase II Randomized, Placebo-Controlled Trial Of Celecoxib In Men Pre-Prostatectomy For Clinically Localized Adenocarcinoma Of The Prostate: Evaluation Of Drug-Specific Biomarker Modulation, N01-CN-95129	Mar 9, 2000	Mar 13, 2006	*									
Pre-Activation Tasks	Mar 9, 2000	Mar 13, 2006	*									
Post-Activation Tasks	Apr 10, 2000	Feb 8, 2003	*									
Accrual Planned	Apr 10, 2000	Jul 10, 2001	*									
Accrual Begins	Sep 19, 2000	Sep 19, 2000	*									
Accrual Completed	Dec 19, 2001	Dec 19, 2001	*									
First Evaluation	Dec 19, 2001	Feb 13, 2002	*									
Study Completed	Feb 13, 2002	Feb 8, 2003	*									

These tasks might include protocol review and approval dates, accrual dates, and amendment dates. Knowledge acquisition is needed to determine which tasks would be most meaningful to DCP.

TaskView- Online Gantt Chart

Task Name	Start Date	Finish Date	Notes	03/00	12/00	09/01	06/02	03/03	12/03	09/04	06/05	03/06
A Phase II Randomized, Placebo-Controlled Trial Of Celecoxib In Men Pre-Prostatectomy For Clinically Localized Adenocarcinoma Of The Prostate: Evaluation Of Drug-Specific Biomarker Modulation, N01-CN-95129	Mar 9, 2000	Mar 13, 2006	*									
Pre-Activation Tasks	Mar 9, 2000	Mar 13, 2006	*									
Post-Activation Tasks	Apr 10, 2000	Feb 8, 2003	*									
Accrual Planned	Apr 10, 2000	Jul 10, 2001	*									
Accrual Begins	Sep 19, 2000	Sep 19, 2000	*									
Accrual Completed	Dec 19, 2001	Dec 19, 2001	*									
First Evaluation	Dec 19, 2001	Feb 13, 2002	*									
Study Completed	Feb 13, 2002	Feb 8, 2003	*									

Colors and symbols can be keyed to specific types of data conditions. For example, a red dot can be used to indicate an estimated date.

TaskView- Online Gantt Chart

Task Name	Start Date	Finish Date	Notes	03/00	12/00	09/01	06/02	03/03	12/03	09/04	06/05	03/06
A Phase II Randomized, Placebo-Controlled Trial Of Celecoxib In Men Pre-Prostatectomy For Clinically Localized Adenocarcinoma Of The Prostate: Evaluation Of Drug-Specific Biomarker Modulation, N01-CN-95129	Mar 9, 2000	Mar 13, 2006	*									
Pre-Activation Tasks	Mar 9, 2000	Mar 13, 2006	*									
Post-Activation Tasks	Apr 10, 2000	Feb 8, 2003	*									
Accrual Planned	Apr 10, 2000	Jul 10, 2001	Notify Medical Monitor when accrual resumes.									
Accrual Begins	Sep 19, 2000	Sep 19, 2000										
Accrual Completed	Dec 19, 2001	Dec 19, 2001										
First Evaluation	Dec 19, 2001	Feb 13, 2002										
Study Completed	Feb 13, 2002	Feb 8, 2003	*									

Users may enter notes and user-defined tasks that are stored in the database and may be viewed by all authorized users.

Additional Possibilities

- Display IND or drug development milestones in addition to clinical trial milestones
- Manage concept and protocol review schedules via the Gantt chart display
- Develop an event notification feature that generates a pop-up message or email when user-defined data conditions are met
- Develop user-definable display options (bar colors and styles, default tasks to display)